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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,937	11/07/2008	Victoria Yamazaki	54795-8003.US00	9737
79975	7590	04/07/2010		
King & Spalding LLP P.O. Box 889 Belmont, CA 94002-0889			EXAMINER KIM, ALEXANDER D	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,937	Applicant(s) YAMAZAKI ET AL.	
	Examiner ALEXANDER D. KIM	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 28 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. By virtue of a preliminary amendment filed on 12/28/2009, claims 4-5 have been amended; and added new claims 13-14. Thus, claims 1-14 are pending in this instant case.

Election

2. Applicant's election of species (CHO cells for claim 4; and epidermal growth factor for claim 5) is acknowledged.

Upon further consideration by the Examiner, the previous Requirement for Restriction Election mailed on 11/25/2009 is vacated.

The instant Office action is a re-restriction requirement that better groups the instant claims. Said requirement is at the discretion of the Examiner (see M.P.E.P. §802 and 37 C.F.R. §1.142) and is deemed appropriate and necessary in view of the complex subject matter of the instant claims and the extensive searching required to identify prior art relating to the instant subject matter.

Restriction

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-6 and 13-14 (in parts), drawn to a method of generating tethered **extracellular** domains of transmembrane proteins comprising: preparing and transfecting an expression vector comprising a 5' signal sequence, a purification epitope tag, a sequence coding for the extracellular domain of a membrane protein, and a 3' anchor sequence.
- II. Claims 1, 4, 6, 7 and 11-13 (in parts), drawn to a method of generating tethered **intracellular** domains of transmembrane proteins comprising: preparing and transfecting an expression vector comprising a 5' myristoylation encoding sequence, a sequence coding for the intracellular domain of a membrane protein, and a 3' purification sequence.
- III. Claims 8-10, drawn to an expression vector comprising a 5' signal sequence, a purification epitope tag, a sequence coding for the extracellular domain of a membrane protein, and a 3' anchor sequence.
- IV. Claims 11-12, drawn to an expression vector comprising a 5' myristoylation encoding sequence, a sequence coding for the intracellular domain of a membrane protein, and a 3' purification sequence

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions are linked by the technical feature of claim 1 drawn to a method of generating tethered extracellular domains of transmembrane proteins comprising: preparing and transfecting an expression vector comprising a 5' signal sequence, a purification epitope tag, a sequence coding for the extracellular domain of a membrane protein, and a 3' anchor sequence. However, this technical feature is not special because it does not constitute an advance over the prior art by Kingsman et al. (WO03/089649; Published Oct. 30, 2003). Kingsman et al. teach an expression vector, methods of use and products obtained therefrom (see top of page 1); wherein the method of use which comprises (a) providing an expression vector (b) transfecting a host cell with the expression vector (see claim 11 and 12 on page 68, for example); wherein the host cell includes CHO mammalian cells (see page 22, line 12). The expression vector by Kingsman et al. includes "an expression vector comprising an amino-terminal tag sequence and a signal sequence operably linked to a nucleotide sequence of interest" (see page 4, lines 12-14); wherein the gene of interest includes the h5T4 human protein with or without the transmembrane domain (see Figure 2 and its description of Figure 2 on page 7). The "extracellular domain" and transmembrane domain (TM) as shown Figure 2 of Kingsman et al. meet the instant "extracellular domain" and instant "anchor sequence" in instant claim 1, respectively,

Groups I-IV lack unity of invention because even though the inventions of these groups require the technical feature of claim 1 as noted above, this technical feature is not special technical feature as it does not make a contribution over the prior art in view of the method by Kingsman et al.

Election of Species

4. This application contains claims directed to the following patentably distinct species: Each mammalian cell (i.e., CHO and HEK-293) is distinct species in Claims 4 and 13 . Each signal sequence recited in Claims 5 and 14 (i.e., epidermal growth factor, insulin, nerve growth factor, platelet-derived growth factor, glucagon, ICAM-1, B7-1, TrkA, platelet-derived growth factor receptor and CD58) is distinct species.

This application contains claims directed to the following patentably distinct species because each cell in claims 4 and 13 has distinct structure by virtue of its genetic composition and the cellular proteins, for example. Each signal sequence recited in Claims 5 and 14 is distinct from each other by virtue of distinct amino acid sequence(s). The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-3 and 6-12 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would

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not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Election

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Notice of Possible Rejoinder

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

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patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEXANDER D. KIM whose telephone number is (571)272-5266. The examiner can normally be reached on 10AM-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alexander D Kim/
Examiner, Art Unit 1656